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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,917	01/11/2001	Ashok Tehim	T8466360US3	9294

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EXAMINER	
HUANG, EVELYN MEI	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/758,917	TEHIM ET AL.	
	Examiner	Art Unit	
	Evelyn Huang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,10,12,13,20,22,24 and 35-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10,12,13,20,22,24 and 35-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-7, 10, 12, 13, 20, 22, 24, 35-38 are pending. Claims 9, 21, 23, 25-34 have been canceled according to the amendment filed on 9-23-2004.

Claim Rejections - 35 USC § 112

2. The rejection for Claims 1-4, 10, 12 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons of record. The rejection is applicable to the new claim 35.

Applicant contends that the examiner has misstated the proviso (ii). The appendix clearly illustrated that each of the 16 compounds does not have benzyl as R1.

On the contrary, the rejection is based on the fact the concept that when R3 is a certain substituent then R1 is a certain substituent is not taught or described in the specification. R1 as benzyl is not described in the specification and therefore does not comply with the written description requirement for R1 is not benzyl.

Claim Rejections - 35 USC § 102

3. The rejection for Claims 1-7, 9-12, 14, 20, 21 under 35 U.S.C. 102(f) is withdrawn upon reconsideration in view of Applicant's Remarks.

Claim Rejections - 35 USC § 103

4. The rejection for Claims 1-7, 9, 20, 21 under 35 U.S.C. 103(a) as being unpatentable over reference AZ2 (PTO-1449; and the information data sheet on the compound provided by Ryan Scientific, Inc.) in view of Gray et al (Analytical Biochemistry, 199, 216(1): 89-96, abstract) and/or Kubinyi (Die Pharmazie, (1995 Oct) 50 (10) 647-62, abstract) is withdrawn because the

claims have been amended to the method of inhibiting a neurtrophin-mediated activity, which has not been taught or suggested by the reference AZ2, Gray or Kubinyi.

5. The rejection for Claims 5, 6, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brana III (4874863, PTO-1449) in view of Bundgaard is withdrawn because the claims have been amended to the method of inhibiting a neurtrophin-mediated activity, which has not been taught or suggested by Brana III or Bundgaard.

6. The rejection for Claims 1-4, 9-12, are rejected under 35 U.S.C. 103(a) as being unpatentable over Sestanj I (3821383, PTO-1449) in view of Malizia (EP 206322, PTO-1449) and Bundgaard is withdrawn upon reconsideration in view of the amendment to the method of inhibiting a neurtrophin-mediated activity and Applicant's remarks.

Duplicate Claims

7. The cancellation of Claim 9 has rendered moot the objection to its being a substantial duplicate of claim 1.

Double Patenting

8. The rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6492380 in view of Bundgaard is withdrawn upon reconsideration in view of Applicant's remarks that there is no common inventor or common assignee between the instant and 6492380.

Claim Rejections - 35 USC § 112

9. The rejection for Claims 1-7, 9-13, 21 under 35 U.S.C. 112, second paragraph, is maintained for reasons of record. Applicant argues that the term 'mediated' would to clear to one of ordinary skill in the art. On the contrary, the term 'mediated' in 'neurotropin-mediated activity' is unclear since 'mediated' does not distinguish between the activity resulting from

activation and the activity resulting from the inhibition of neurotropin, nor would it define how far upstream or downstream from the action of neuotropin would still be considered to be within the scope of the claims.

Claim Rejections - 35 USC § 112

10. The rejection for Claims 1-7, 10, 12 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons of record. The rejection is applicable to amended claims 13, 20, 22, 24, 35-38.

Applicant maintains that 'the conflicting diseases' are not understood as a discussion of the functions and the roles of neurotropins in certain diseases and conditions have been discussed.

The 'neurotropin-mediated activity' encompasses conflicting conditions (those resulting from the activation by neurotropin and those resulting from inhibition of neurotropins). Furthermore 'neurotropin-mediated activity' and reaches out to conditions or diseases not yet discovered, a full description of which is not found in the specification.

Claim Rejections - 35 USC § 112

11. The rejection for Claims 1-7, 10, 12 under 35 U.S.C. 112, first paragraph is maintained for reasons of record. The rejection is applicable to amended claims 13, 20, 22, 24, 35-38. The specification is enabling for the use of the inventive compound for treating pain.

Claims directed to mediating a biological pathway are devoid identifiable utility and are therefore not useful. Unless the pathway at issue is critical to treating some condition and the pathway modification and disease treatment are inexorably linked, such pathway modification is devoid of utility. The instant claims directed to neurotropin-mediated activity, such as binding to a $p75^{NGFR}$ receptor, binding to a trk receptor, neuron process formation, neurite outgrowth or enzyme induction, without the end result would therefore have no practical utility unless the inhibition and the treatment of the diseases/conditions are inexorably linked. Since the claims as recited embrace any degree of inhibition, which may or may not inexorably linked to the

treatment of diseases/conditions, the scope of the claims is therefore not commensurate with that of the objective enablement, especially in view of the absence of a full written description of the as yet unidentified conditions/activities/disorders which the recited mechanism reaches out to. One of ordinary skill in the art therefore would not be able to use the inventive compound as claimed without undue experimentation.

Applicant argues that the specification has provided ample experimental evidence that there is a correlation between inhibition of NGF binding and the biological response.

On the contrary, the working example is limited to the inhibition of NGF binding and the inhibition of neurite outgrowth and the treatment of neuropathic pain. Since the neurotropin family includes NGF, neurotropin 3 and neruotrophin 4/5 etc, each with different binding characteristics to different trk receptors, one of ordinary skill in the art would have no basis to extend the NGF binding to all other neurotropins, nor would one of ordinary skill in the art be able to extrapolate the NGF binding data to various in vivo situations involving different target tissues, and all the diseases as recited.

In view of the high degree of unpredictability in the neurotropin inhibitor art (Jaen, columns 14-15, Table I; LeSauteur, abstract; page 6567, Table II, Table III), and the limited working examples, Applicant's assertion that all the inventive compounds would be effective in treating any neurotropin-mediated activity (including those requiring the activation and those requiring the inhibition of neurotropin, and those as yet undiscovered activities/ diseases/ conditions), does not commensurate with the scope of the objective enablement. Since insufficient teaching and guidance have been provided in the specification, one of ordinary skill in the art would not be able to use the inventive compounds as claimed without undue experimentation except for using the inventive compound for treating pain.

Conclusion

12. No claims are allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Evelyn Huang
Primary Examiner
Art Unit 1625

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